BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
YEM CHIN *et al.*

Application/Control No.: 09/963,676 Group Art Unit: 3731

Filed: September 27, 2001 Examiner: Darwin P. Erezo

For: **METHOD AND APPARATUS FOR MEASURING AND CONTROLLING BLADE DEPTH OF A TISSUE CUTTING APPARATUS IN AN ENDOSCOPIC CATHETER**

REPLY BRIEF
(37 CFR §41.41)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief, in accordance with 37 CFR §41.41, is filed in response to the Examiner's Answer mailed March 8, 2007 ("Answer").

I. APPEAL BRIEF ACKNOWLEDGED AS ADDRESSING REQUIRED MATTERS

The first seven sections of the Answer acknowledge that the Appeal Brief filed November 17, 2006 addresses those matters required by 37 CFR §41.37(c)(1)(i)-(vi) & (viii). It further is acknowledged in the Answer with respect to these seven matters that they are correctly addressed in the Appeal Brief where the Examiner can confirm facts from the prosecution history for this application.

II. ASSERTED PRIOR ART AND PENDING CLAIM REJECTIONS

Sections 8 and 9 of the Answer respectively list prior art patents of record that are asserted as evidence in support of outstanding claim rejections, and the grounds of rejection applied to the appealed claims. The patents of record listed in section 8 are: U.S. Patent 5,425,376 ("Banys *et al.*"); U.S. Patent 6,574,497 ("Pacetti"); and U.S. Patent 4,588,399 (Nebergall *et al.*"). The grounds of rejection set out in section 9 of the Answer are a verbatim reproduction of the rejections reported in the final Office action mailed February 6, 2006. No new grounds are asserted.

III. RESPONSE TO ARGUMENT

A. Banys *et al.* In View of All Other Cited Prior Art Fails To Render Obvious Method Claims 27, 28 and 31 or Apparatus Claims 35-37 and 29

In section 10 of the Answer, the Examiner argues that Banys *et al.* disclose "a tissue cutting device that is disposed in a catheter lumen, the cutting device disposed for extension out of an opening of the catheter lumen." (Ans., p. 5) The Examiner's argument is flawed.

What Banys *et al.*, however, nowhere disclose or suggest is that their cutting edge 27 within the lateral opening 28 is in anyway capable of being a tissue cutting device without further structure Banys *et al.* only disclose with respect to a tissue cutting device:

> The cannula can also have a sharp edge on its distal end, so that advancing the canuala along the needle can cut off the tissue sample that has been maneuvered into the lateral opening of the needle. The sharp edge on the end of the cannula can be shaped to perfectly align with the closed front end of the needle during insertion into the target tissue, to minimize trauma to the surrounding tissue. (col. 2, lines 52-59)

Banys *et al.* explicitly disclose a "[d]istal end 56 of cannula tube 44 [having] a sharp cutting edge *to assist in cutting* a sample from the selected tissue" (Emphasis added, col. 5, lines 12-14). Additionally disclosed is needle 16 having "[l]ateral opening 28... formed with at least one sharp cutting edge 27 near the distal end of opening 28, *to assist in the cutting* of a sample from the selected tissue." (Emphasis added, col. 5, lines 6-8) It only is the Banys *et al.* cannula distal end 56 having a cutting edge in combination with the cutting edge 27 at the distal end of lateral

opening 28 that is disclosed in the patent as providing any device capable of cutting tissue. This combination is disclosed as only existing at the literal end of cannula 14 where cannula distal end 56 and cutting edge 27 are brought together. The requirement to bring cannula distal end 56 into combination with cutting edge 27 precludes any Banys *et al.* disclosed device of having a tissue cutting device that is *disposed in* a catheter lumen or a device capable of having a cutting device *disposed for extension* out of an opening of the catheter lumen.

In spite of these facts, it is stated in the Answer that the Banys *et al.* "*cutting edge of the needle*...is still fully capable of cutting tissue on its own and is capable of being disposed outside the lumen of the cannula." (Emphasis in original, Ans., p.6) Banys *et al.*, not only nowhere disclose or suggest that cutting edge 27 is "fully capable of cutting tissue on its own," but instead only disclose a cutting edge 27 requires other structure to provide a device capable of cutting tissue. What Banys *et al.* exclusively disclose is that cutting edge 27 can "assist in cutting of a sample from the selected tissue" (col. 5, lines 6-8). The assistance Banys *et al.* disclose is that cutting edge 27 and cannula distal end 56 must be brought together.

The conclusion that cutting edge 27 is "fully capable of cutting tissue on its own" not only is without basis from Banys *et al.*, it is in contradiction to Banys *et al.* disclosures. The assertion of this conclusion is first made in the Answer. As such, the record is silent on factual bases for this conclusion as asserted in the Answer, and, therefore, if the conclusion is to be maintained those facts must be within the personal knowledge of the Examiner who signed the Answer and evidence concerning those facts are required to be submitted. In order to continue with the conclusion, which was first asserted in the Answer, and have it be made of record the Office regulations, i.e., 37 CFR §1.104(d)(2), provide that an affidavit signed by the Examiner is to be submitted setting out all facts within the personal knowledge of the Examiner that are relied on in the Answer. The regulation further provides that such as affidavit "shall be subject to contradiction or explanation by the affidavits of the applicant and other persons." Continuing this appeal without such an affidavit signed by the Examiner and other submitted affidavits or equivalent evidence would result in an empty evidentiary record to sustain the asserted conclusion and dictates that the conclusion be disregarded by the Board.

With respect to Banys *et al.* failing to disclose or suggest a needle knife, the assertion in the Answer that cutting edge 27 in lateral opening 28 "is viewed as a needle knife" (Ans, p.7) fails for the reasons set out above. Specifically, Banys *et al.* disclose that cutting edge 27 in lateral opening 28 can "assist in the cutting of a sample from the selected tissue" (col. 5, lines 6-8). Nowhere do Banys *et al.* disclose or suggest that their cutting edge 27 in lateral opening 28 can of itself be disposed so as to be any knife edge capable of cutting tissue on its own. Banys *et al.* therefore fail to disclose a needle knife.

In contradiction to the unsupported bald statement in the Answer that Banys *et al.* needle 16 "is viewed as a needle knife," the Banys *et al.* patent consistently and repeatedly discloses their needle 16 to be a biopsy needle and not any type of device other than a biopsy needle, e.g., see col. 2, lines 41-45 and col. 4, lines 15-16. Biopsy needles and needle knives are used differently, and they are used to perform different procedures. Banys *et al.* without any varying suggestion exclusively disclose insertion within a body of their needle 16 as an interacting part in combination with cannula 14 so that a tissue sample can be detached from the body and this detached tissue is brought out of the body through a lateral opening in needle 16, e.g., see col. 2, lines 52-59, and col. 5, line 28 to col. 6, line 32. Such design and use for needle 16 as disclosed by Banys *et al.* are limited to biopsy needles, not needle knives. As the plain meaning of the words dictate, a needle knife is a device capable of dividing, i.e., cutting, something such as tissue. A needle knife is a complete device in itself that is used for cutting. A needle knife does not require additional parts such as interacting parts, as does the Banys *et al.* biopsy needle, to accomplish cutting. Said in terms of medical procedures, a biopsy needle is used for performing diagnostic procedures that require tissue samples to be removed from patients, and needle knives are used for therapeutic or other medical procedures requiring cutting such as a sphincterotomy - division of a Sphincter of Oddi (Application Abstract). The Banys *et al.* needle 16 is a biopsy needle, and it is not a needle knife nor is it a device suggestive of a needle knife.

B. Pacetti In View Of All Other Cited Prior Art Fails To Render Appealed Claims Obvious

The Answer in addressing Pacetti only states without explanation that the Appeal Brief provides "the same arguments as cited in the arguments for Banys reference." (Ans., p.7) Nothing further is stated in the Answer.

The Appeal Brief in section VII(c)(5) sets out why Pacetti indeed does not remedy Banys *et al.* deficiencies. The above discussions here in section III(A) are directed to Banys *et al.* failures that despite arguments asserted in the Answer continue to confirm that Banys *et al.* in view of Pacetti do not render obvious appealed claimed subject matter.

This conclusion as to Banys *et al.* in view of Pacetti failures also encompasses Pacetti's failure to disclose or suggest a needle knife, which is not disputed in the Answer.

C. Nebergall *et al.* In View Of All Other Cited Prior Art Fails To Render Appealed Claims Obvious

In part, the Answer without further explanation states with respect to Nebergall *et al.* that the Appeal Brief provides "the same arguments for the Banys reference...." The Appeal Brief in section VII (D) sets out why Nebergall *et al.* does not remedy failures in Banys *et al.* or Pacetti or any proper combination of these references. These arguments continue to be maintained.

Then it is asserted in the Answer that the Appeal Brief argues "there is no motivation to combine the teachings of Nebergall with Banys and Pacetti." As an introduction to the matter, it is pointed out in the Appeal Brief: "The Examiner alleges that one skilled in the art would want to 'determine the location of the [Banys *et al.*] cutting device relative to the cannula.'" (Appeal Brief, section VII(D), citing February 6, 2006 Final Office Action, p. 4) Then explained in the Appeal Brief is the fact that tissue only is cut at the lateral opening 28 of the Banys *et al.* needle 16 when the lateral opening 28 is brought to the cannula distal end of 56. In response to Appellant's arguments, the Answer states::

> [T]his is not persuasive because the operation of the device of Banys *et al.* requires that the lateral opening 28 of the needle be exposed from the distal end of the cannula in order to receive a tissue to be sampled for biopsy. Therefore, one

> of ordinary skill in the art would have been motivated to provide radiopaque indicia on the cannula because it allows the cannula to be used as a reference point in order to determine the distance between the lateral opening of the needle and the distal end of the cannula. This would allow a practitioner to visually verify that the lateral opening of the needle is spaced away from the distal end of the cannula. (Ans., p. 7)

Again, however, the Banys *et al.* disclosure simply contradicts the Examiner's assertions. Banys *et al.* disclose a positive mechanical system to determine the distance between the lateral opening of the needle and the distal end of the cannula. This mechanical system is shown in FIG. 5 of the patent and its operation is described at col. 6, lines 3-7:

> [T]he physician can...pull on hub flange 48 to withdraw cannula 14 from needle 16, until follower pin 52 reaches the proximal end of withdrawal groove 31, as shown in FIG. 5. This exposes lateral opening 28 to the selected tissue.

Banys *et al.* make no disclosure or suggestion for visual confirmation of exposing lateral opening 28 to tissue because moving follower pin 52 to the proximal end of withdrawal groove 31 produces that exposure in the same amount as pin 52 is moved along withdrawal groove 31.

Compounding these facts is the matter that Banys *et al.* disclose "cannula 14 consists of a hollow *steel* cannula tube 44." (Emphasis added, col. 5, lines 9-10) In being a "*steel* cannula tube" the Banys *et al.* cannula is in and of itself radiopaque. Therefore, how can there be any motivation to provide any radiopaque indicia on the radiopaque Banys *et al.* cannula? There is none! Further, radiopaque indicia is not needed because of the positive mechanical system, and any added radiopaque indicia would be understood to be indistinguishable from the radiopaque steel cannula structure.

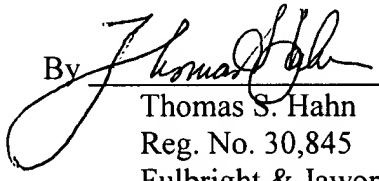
The very disclosures in Banys *et al.*, accordingly, confirm there is no motivation to combine Banys *et al.* with Pacetti and Nebergall et al.

CONCLUSION

Accordingly, for the reasons set out in the Appeal Brief and this Reply Brief, none of the appealed claims are rendered obvious by the prior art. Therefore, the Examiner's rejections should be reversed.

Date: May 8, 2007

Respectfully submitted,

By 

Thomas S. Hahn
Reg. No. 30,845
Fulbright & Jaworski L.L.P.
801 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2623
Telephone: 202.662.4678

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CONCLUSION

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Date: May 8, 2007

Respectfully submitted,

By _____

Thomas S. Hahn
Reg. No. 30,845
Fulbright & Jaworski L.L.P.
801 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2623
Telephone: 202.662.4678